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Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane,  
Rockville, MD 20857

In re: Patent Term Extension  
Application for  
U.S. Patent No. 5,859,006

Attention: Claudia Grillo

Dear Ms. Axelrad:

This communication acknowledges receipt of your letter of October 19, 2004, indicating that Cialis® was subject to a regulatory review period before its first permitted commercial marketing as required by 35 U.S.C. 156(f)(1).

The patent claims of U.S. Patent No 5,859,006 claim a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Kery Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: James J. Napoli  
Marshall, Gerstein & Borun  
233 South Wacker Drive  
Chicago, IL 60606

RE: CIALIS® (tadalafil)  
Docket No. 04E-0413